Accurate across patient populations

- Effective in challenging patient populations¹
  - Immunocompromised
  - BCG-vaccinated
- Only TB test with sensitivity and specificity > 95%¹
  - Sensitivity: 95.6%
  - Specificity: 97.1%
- FDA-approved borderline zone provides test resolution for results around the cut-off point², ³

Consistent results

- Invalid rate of 0.6% in a study of > 645,000 tests²
- 98.9% concordance and 0.8% mean conversion rate in a study of > 42,000 healthcare worker serial tests⁴

One tube with no refrigeration¹

- Standard phlebotomy
- One visit
- No on-site pre-analytical steps
- No on-site incubation or refrigeration

---

**THE SCIENCE BEHIND THE T-SPOT®.TB TEST**

1. Whole blood vs Isolated cells
   
   A blood specimen is collected using routine phlebotomy and a standard blood collection tube from which a subset of white blood cells, known as peripheral blood mononuclear cells, are isolated. The cells are washed, counted and normalized to create a standard cell suspension.

2. ESAT-6 and CFP10 antigens
   
   A standard number of cells are added into specially designed plates and stimulated with TB-specific antigens, ESAT-6 and CFP10. Cells responding to these antigens release interferon-gamma.

3. Secondary enzyme labeled antibody
   
   Interferon-gamma antibodies are used to directly capture interferon-gamma as it is released by the cells. A secondary enzyme labeled antibody is added and binds to the captured interferon-gamma.

4. Spots produced where interferon-gamma was released
   
   A detection reagent is added and reacts with the enzyme labeled antibody. This reaction produces spots, which are a footprint of where the interferon-gamma was released. Spots are then enumerated.
Interpretation of results

- Interferon-gamma is captured and presented as spots from T cells sensitized to TB infection
- Results are interpreted by subtracting the spot count in the negative (NIL) control from the spot count in Panels A and B
  - Positive ≥ 8 spots
  - Negative ≤ 4 spots
  - Borderline 5, 6 or 7 spots
  - Invalid
- The inclusion of a borderline category is intended to reduce the likelihood of false-positive or false-negative results around the test cut-off

Note: It is recommended that borderline and invalid results be retested with a new specimen

Unique CPT® code

The T-Spot.TB test is the only commercially available TB blood test appropriate to be submitted under CPT code 86481.1,6 The T-Spot.TB test is a standardized test that requires cell enumeration.1

<table>
<thead>
<tr>
<th>CPT code</th>
<th>86481*</th>
<th>86480*</th>
<th>86480*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable test</td>
<td>The T-Spot.TB test</td>
<td>QuantiFERON®-TB Gold Plus (QFT®-Plus)</td>
<td>LIAISON® QFT-Plus</td>
</tr>
<tr>
<td>Description</td>
<td>Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension</td>
<td>Tuberculosis test, cell mediated immunity measurement of gamma interferon producing antigen response</td>
<td>Tuberculosis test, cell mediated immunity measurement of gamma interferon producing antigen response</td>
</tr>
</tbody>
</table>

* The listed CPT codes reflect Oxford Immunotec’s general interpretation of CPT coding requirements and are provided for informational purposes only.

OXFORD IMMUNOTEC DOES NOT PROVIDE CODING ADVICE AND ASSUMES NO RESPONSIBILITY FOR BILLING ERRORS DUE TO RELIANCE ON CPT CODES LISTED IN MATERIALS PROVIDED BY OXFORD IMMUNOTEC. It is the responsibility of the billing laboratory to determine the correct CPT code to use in light of the particular circumstances.

REFERENCES: